

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

ASTELLAS US LLC, ASTELLAS PHARMA)
US, INC., and GILEAD SCIENCES, INC.,)

Plaintiffs,)

v.)

APOTEX INC.,)

Defendant.)

No. 18-cv-01675-CFC (Consolidated)

**OPENING BRIEF IN SUPPORT OF APOTEX INC.'S
MOTION TO DISMISS COUNT II OF THE COMPLAINT**

Dated: May 28, 2019

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I. NATURE AND STAGE OF PROCEEDING

Plaintiffs' complaint alleges infringement of U.S. Patent 9,085,601 ("601 patent"). *See* Count II, D.I. 1 at ¶¶ 31-35. On November 30, 2018, Apotex moved to dismiss the complaint based on improper venue and the first-filed rule. D.I. 13. On May 8, 2019, the Court denied Apotex's motion based on the dismissal of Apotex's California complaint. D.I. 62.¹

II. SUMMARY OF ARGUMENT

Plaintiff Gilead has surrendered the 601 patent to the U.S. Patent Office. Because a surrendered patent is void and unenforceable, it cannot be infringed. *See, e.g., Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 827 (Fed. Cir. 1984) ("An original patent **cannot be infringed** once a reissue patent has issued, for the original patent is surrendered."); *Pfizer Inc. v. Apotex Inc.*, 731 F. Supp. 2d 741, 746 (N.D. Ill. 2010) ("Once the original patent is surrendered, it **cannot be infringed** because the original claims are dead.") (internal quotes omitted); *Mobile Shelter Sys. USA, Inc. v. Grate Pallet Sols., LLC*, 845 F. Supp. 2d 1241, 1261 (M.D. Fla. 2012) ("It is **black letter law** that an original patent is **void and unenforceable** after the patent is surrendered to the Patent Office in a reissue proceeding.") (emphasis added).

Accordingly, Apotex respectfully requests that the Court dismiss Count II of Plaintiffs' complaint for failure to state a claim. FED. R. CIV. P. 12(b)(6).

III. STATEMENT OF FACTS

On March 19, 2019, Gilead surrendered the 601 patent to the U.S. Patent Office. *See, e.g.,* <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u>

¹ On February 20, 2019, Apotex filed a Motion for Reconsideration based on the California Court's clear legal errors. *Apotex v. Gilead*, 18-cv-06475 (N.D. Cal.), D.I. 58. Apotex's motion remains pending.

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IV. LEGAL STANDARDS

This Court is well-versed in the standard for Rule 12(b)(6) dismissal. *See, e.g., Mosiman v. Madison Cos., LLC*, No. 17-cv-01517-CFC, 2019 WL 203126 (D. Del. Jan. 15, 2019). In order to survive a motion to dismiss under Rule 12(b)(6), “the complaint must contain sufficient factual matter ‘to state a claim to relief that is plausible on its face.’” *Id.* at *2 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009)). The Court’s review of the record may include “the allegations in the complaint, exhibits attached to the complaint, documents incorporated by reference, items subject to judicial notice, and matters of the public record.” *Id.* (citing *D.M ex rel. Ray v. Phila. Housing Auth.*, 613 F. App’x 187, 189 (3d Cir. 2015)). Furthermore, “a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss” without converting the motion to a motion for summary judgment. *Benihana of Tokyo Inc. v. Benihana Inc.*, No. 10-cv-01051-SLR, 2011 WL 3861897, at *2-3 (D. Del. Sept. 1, 2011) (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)) (considering a public USPTO record). “In assessing the plausibility of a claim, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff.” *Mosiman*, 2019 WL 203126, at *2 (citing *In re Rockefeller Ctr. Prop., Inc. Sec. Litig.*, 311 F.3d 198, 215 (3d Cir. 2002)). But this Court is not “obligated to accept as true . . . allegations that are ‘self-evidently false.’” *Tuppeny v. City of Wilmington*, No. 13-cv-01556-LPS, 2015 WL 1383864, at *2 (D. Del. Mar. 24, 2015) (quoting *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996)).

* * *

V. ARGUMENT

Because Gilead has surrendered the 601 patent, it is void and unenforceable, and cannot be infringed. *See, e.g., Seattle Box*, 731 F.2d at 827 (“An original patent cannot be infringed² once a reissue patent has issued, for the original patent is surrendered.”); *Pfizer*, 731 F. Supp. 2d at 746 (“Once the original patent is surrendered, it cannot be infringed because the original claims are dead.”) (internal quotes omitted); *Mobile*, 845 F. Supp. 2d at 1261 (“It is black letter law that an original patent is void and unenforceable after the patent is surrendered to the Patent Office in a reissue proceeding.”); *Voter Verified, Inc. v. Election Sys. & Software, Inc.*, 745 F. Supp. 2d 1237, 1246 (M.D. Fla. 2010) (“Once a reissue patent has been granted, the original patent cannot be infringed for the original patent is surrendered.”) (internal quotes omitted).

Plaintiffs, therefore, cannot state a claim for infringement of the 601 patent. *See, e.g., Pfizer*, 731 F. Supp. 2d at 746 (“[W]here a patentee seeks to surrender an original patent in favor of a single reissue patent, the matter is very straightforward: the surrender of the original patent takes effect when the reissue patent is granted, and after reissue, ***the original patent is no longer enforceable***. In other words, in the case of a single reissue patent, surrender and reissuance go hand-in hand, and ***the original patent is invalid*** after the date of reissue.”); *Mobile*, 845 F. Supp. 2d at 1261 (finding that, because the original patent was surrendered, “there is ***no legal basis*** for Plaintiff’s claims of patent infringement”); *Voter Verified*, 745 F. Supp. 2d at 1246-47 (“[T]he original patent must be surrendered to the PTO in order for the reissue patent to be granted, ***rendering the original patent unenforceable***.”) (emphasis added). Thus, Apotex respectfully requests that the Court dismiss Plaintiffs’ claim for infringement of the surrendered 601 patent.

² Despite this binding precedent, Plaintiffs currently assert the 601 patent against Apotex’s ANDA Product. *See, e.g., Plaintiffs’ Paragraph 4(a) Disclosure* (March 21, 2019). Plaintiffs have no good faith basis to do so.

VI. CONCLUSION

According to Rule 12(b)(6), Count II of Plaintiffs' complaint (D.I. 1) should be dismissed for failure to state a claim upon which relief can be granted.³

* * *

Dated: May 28, 2019

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³ If the Court grants Apotex's motion, Apotex's responsive pleading will be due within 14 days after notice of the Court's action. *See, e.g.*, FED. R. CIV. P. 12(a)(4)(A); *Circuit City Stores, Inc. v. Citgo Petroleum Corp.*, No. 92-cv-07394, 1994 WL 483463, at *4 (E.D. Pa. Sept. 7, 1994); 5B WRIGHT & MILLER, FED. PRAC. & PROC., CIV. § 1346 (3d ed.).